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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,124	03/31/2006	Dominique M. Freeman	PEL-2784	4918
77845	7590	12/30/2009		
Goodwin Procter LLP Attn: Patent Administrator 135 Commonwealth Drive Menlo Park, CA 94025-1105			EXAMINER EDWARDS, LYDIA E	
			ART UNIT 1797	PAPER NUMBER
			MAIL DATE 12/30/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/541,124	Applicant(s) FREEMAN ET AL.	
	Examiner LYDIA EDWARDS	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/31/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 29 is/are allowed.
- 6) ☒ Claim(s) 1-28, 30-33 is/are rejected.
- 7) ☐ Claim(s) 34-40 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :6/30/2005, 3/16/2007, 4/3/2007, 4/22/2007, 6/10/2007, 6/23/2007, 8/26/2008, 10/17/2008, 11/17/2008, 1/14/2009, 3/26/2009, 5/27/2009, 9/15/2009, 12/10/2009.

DETAILED ACTION

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 26, 30, and 31 of this application conflict with claims 19, 22, and 23 of Application No. 10540912. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Claims 26 and 30-31 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 19 and 22-23 of copending Application No. 10540912. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined

application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-23, 25 and 27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 10540912. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn towards a device for use in a metering device for measuring analyte levels in a sample fluid, said device comprising: a cartridge; a plurality of analyte detecting members mounted on said cartridge; wherein said cartridge does not include any penetrating members; wherein said cartridge has a radial disc shape; and wherein said cartridge is sized to fit within said metering device.

This is a provisional obviousness-type double patenting rejection.

Claim 24 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 17 of copending Application No. 10540912. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn towards a cartridge having a plurality of sample chambers; a

plurality of analyte detecting members; wherein at least one of said analyte detecting members forms a portion of one wall of one of said plurality of sample chambers.

This is a provisional obviousness-type double patenting rejection.

Claim 28 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 21 of copending Application No. 10540912. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn towards a method for determining a concentration of an analyte in body fluid, comprising: collecting a sample of body fluid of about 500 nL or less; covering an electrochemical sensor with at least a portion of the sample; determining the concentration of the analyte in the sample.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding Claims 5-8, the examiner is unclear as the claim language further limits the device of claim 1. Is claim 5 intended to be a use claim?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4-14, 17-18 24, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simons et al. (U.S. 6036924) in view of Lum et al. (GB 2335990) further in view of Betts et al. (US 5405510).

Simons et al. ('924) discloses a cartridge (246) having a plurality of cavities (244), a plurality of penetrating members (216 connected to 224) which are contained at least partially in the cavities and are slidably movable to extend outward from the openings on the cartridge (col. 5 lines 16-26). Simons et al. also discloses a plurality of chambers each associated with a cavity that are positioned along an outer periphery of the cartridge. An analyte detecting member is associated with each chamber and forms a portion of one wall of the plurality of chambers (Fig. 3A, 220 and col. 8 lines 19-29). Simons et al. discloses that the test area can be the absorbent

material 21.8 or the surface beneath it which is a wall of the chamber. Simons et al. discloses the invention as stated above regarding claim 1 and further discloses that the chamber is positioned substantially adjacent an outer periphery of the cartridge (Fig. 6D) and at least one opening in one of the chambers which leads fluid along a fluid path toward an analyte detecting member (col. 8 lines 19-22 and lines 29-35 and col. 7 lines 40-49).

Simons fails to disclose a position sensor coupled to the plurality of penetrating members, the position sensor utilizing position information of a penetrating member to determine a depth of penetration through a skin surface.

Lum et al. ('990) discloses that it is old and well known in the art to use a position sensor coupled to a penetrating member, the position sensor utilizing the position information of the penetrating member to determine the depth of penetration through the skin. In particular, Lum et al. discloses a penetrating member that uses a sensor that senses the different impedance values of the different layers of skin to determine information on which layer of skin the penetrating member is positioned within (p. 3, lines 4-7). Lum et al. further discloses that this information helps to minimize the trauma and pain of over-penetration as well as avoid the frustration and pain of unsuccessful blood sampling because of inadequate penetration (p. 3, lines 16-23). Lum et al. discloses that these advantages are especially pertinent to patients such as diabetics, who have to sample blood often (p. 1, lines 22-23). Simons et al. disclose that the cartridge of their body fluid sampling device may be used in conjunction with a glucometer (see abstract).

Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Simons et al. to include a position sensor coupled to the plurality of penetrating members, the position sensor utilizing position information of a penetrating member to determine a depth of penetration through a skin surface as made obvious by Lum et al. in order to avoid the problems associated with over-penetration or inadequate penetration.

Simons fails to disclose a memory on said device.

Betts et al. ('510) discloses memory on an analyte measuring system for fluid samples (Col 5, lines 16-65 and Col 6, line 34-59)

It would have been obvious to one of ordinary skill in the art to modify the device of Simons et al. and Lum et al. with a memory on the device as taught by Betts et al. to employ a means for calibration and analysis of the samples.

With respect to the intended use limitations, the device disclosed by the combination of Simons, Lum and Betts is structurally the same as the instantly claimed and is capable of providing the operating conditions listed in the intended use section of the claim. Note statements of intended use carry no patentable weight when the structure of the Claim has been met by the prior art reference.

Regarding Claims 5-14, and 17-18, with respect to the intended use limitations, the device disclosed by the combination of Simons, Lum and Betts is structurally the same as the instantly claimed and is capable of providing the operating conditions listed in the intended use section of the claim. Note statements of intended use carry no patentable weight when the structure of the Claim has been met by the prior art reference.

Allowable Subject Matter

Claim 29 is allowed.

Regarding Claim 29, prior art fails to disclose a method comprising: providing a cartridge having a plurality of wells; depositing an emulsion in the wells; scraping away emulsion from tops of the wells, in order to level the amount of emulsion in each well.

Claims 34-40 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Regarding Claims 34-40, prior art fails to disclose the device of claim 33 further comprising an optical system.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYDIA EDWARDS whose telephone number is (571)270-3242. The examiner can normally be reached on Mon-Thur 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571.272.1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LYDIA EDWARDS/
Examiner
Art Unit 1797

LE

/Walter D. Griffin/
Supervisory Patent Examiner, Art Unit 1797